IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

PFIZER INC., PFIZER LIMITED, and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs, v. TIGER PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 1:14-cv-1501-AJT-TRJ

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

Pursuant to this Court's Rule 16(b) Scheduling Order (Dkt. 28), the parties' stipulated Discovery Plan (Dkt. 21), and the Stipulated Order Extending Time for Claim Construction Briefing (Dkt. 43), plaintiffs Pfizer Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer") submit this brief in support of Pfizer's proposed constructions of the disputed claim terms of Pfizer's U.S. Patent No. 6,124,363 (the "'363 patent") (Ex. A)[1] as identified in the Joint List of Agreed and Disputed Claim Terms (Dkt. 38).

BACKGROUND

This is a patent infringement case brought by Pfizer against Tiger Pharmaceuticals, LLC ("Tiger") under the Hatch-Waxman Act alleging that Tiger has infringed the '363 patent by filing an Abbreviated New Drug Application with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Pfizer's Tikosyn®

[1] "Ex. __" refers herein to exhibits to the declaration of Soumitra Deka.

product prior to the expiration of the '363 patent. Pfizer's Tikosyn capsules are approved by the FDA for treatment of patients with atrial fibrillation/atrial flutter. The active ingredient in Pfizer's Tikosyn capsules and, therefore, in Tiger's proposed generic products, is dofetilide.

The '363 patent discloses and claims certain dofetilide "polymorphs." Polymorphism refers to the property of some chemical compounds to exist in multiple distinct physical forms. *See Pharmaceutics: The Science of Dosage Form Design*, 157 (Michael E. Aulton ed., 1988) (Ex. B); (Chyall Decl. at ¶ 15).[2] While two polymorphs of the same chemical compound are comprised of the same atomic components, their configurations differ. (*See* Ex. B at 71); (Chyall Decl. at ¶ 15). In particular, crystal polymorphs result from the ability of the molecules of a compound to form solids consisting of different repeating patterns of molecules with different orientations and placements. (*See* Ex. B at 71); (Chyall Decl. at ¶ 16). The differences in the crystal structures can affect the physical properties of the substance, including the melting point and x-ray diffraction spectrum. (*See* Ex. B at 71); (Chyall Decl. at ¶¶ 17-19).

The '363 patent explains that "[d]ofetilide is a very potent drug" that is administered in low dosages. (Ex. A. at 1:45-46). Thus, dofetilide must be produced having a small particle size to ensure a homogeneous blend in the capsules provided to patients. (*Id.* at 1:46-49). However, as set forth in the patent, dofetilide prepared using the methods disclosed in the prior art produced a mixture of polymorphs which would require extensive processing, such as milling, in order to obtain uniform dofetilide of appropriately small particle size. (*Id.* at 1:50-57). Accordingly, Pfizer's researchers investigated and ultimately developed methods of easily and reproducibly preparing dofetilide having the required small particle size without any need for milling. (*Id.* at 1:60-65).

[2] "Chyall Decl." refers to the accompanying declaration of Leonard J. Chyall, Ph.D.

This work led to the invention claimed in the ’363 patent. Specifically, the Pfizer researchers invented methods of making substantially pure dofetilide polymorphs which crystallize with a consistently small particle size and do not require milling before use in a capsule formulation. (*Id.* at 2:3-7). The ’363 patent claims are directed to those substantially pure forms of dofetilide, identified as P162, P143, and P162a.

The ’363 patent discloses that dofetilide polymorphs can be characterized or identified by the results of analytical chemistry tests, including differential scanning calorimetry (DSC), powder X-ray diffraction, and infrared spectrum analysis. For example, claim 1 of the ’363 patent recites: “Substantially pure, crystalline, dofetilide polymorph P162 which is characterised by differential scanning calorimetry (DSC) in which it exhibits an endothermic thermal event at about 162° C.” Independent claims 11 and 17 have a similar structure, except they are directed to dofetilide polymorphs P162a and P143, respectively. The ’363 patent includes dependent claims directed to further analytical characterizations of the dofetilide polymorphs, processes for preparing the dofetilide polymorphs, pharmaceutical compositions comprising the dofetilide polymorphs, and methods of treating cardiac arrhythmia and heart failure by administering the dofetilide polymorphs.

ARGUMENT

POINT I

THE LAW OF CLAIM CONSTRUCTION

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)); *see also Straight Path IP Grp., Inc. v. Bandwidth.com, Inc.*, No. 1:13-CV-932 AJT/IDD, 2014 WL 793528, at *2-4 (E.D. Va. Feb. 25, 2014). "The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996)).

"[T]he words of a claim 'are generally given their ordinary and customary meaning,'" which is "the meaning the term would have to a person of ordinary skill in the art at the time of the invention." *Phillips*, 415 F.3d at 1312-13. This is because "inventors are typically persons skilled in the field of the invention" and "patents are addressed to and intended to be read by others of skill in the pertinent art." *Id.* at 1313.

The process of claim construction begins with the words of the claims themselves. *Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1315 (Fed. Cir. 2006). Because the claims "are part of 'a fully integrated written instrument'" they "'must be read in view of the specification, of which they are a part.'" *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 978-79). "[A] court 'should also consider the patent's prosecution history, if it is in evidence.'" *Id*. at 1317 (quoting *Markman*, 52 F.3d at 980). The prosecution history,

which is "part of the 'intrinsic evidence,' consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Id*. "Although the specification may aid the court in interpreting the meaning of disputed language in the claims, particular embodiments and examples appearing in the specification will not generally be read into the claims." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988).

Beyond the patent's intrinsic record, the court may also examine "extrinsic evidence" consisting of "'all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317 (quoting *Markman*, 52 F.3d at 980); *see also Straight Path IP Grp.*, 2014 WL 793528, at *2.

Claims must also be construed in a manner that avoids rendering other claims redundant or meaningless. *See Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1327 (Fed. Cir. 2007); *see also Boss Indus., Inc. v. Yamaha Motor Corp. U.S.A.*, 333 F. App'x 531, 542 (Fed. Cir. 2009) (refusing to construe a claim in a manner that would render the limitation "essentially meaningless" in light of other claims).

In addition, the Federal Circuit has stated that "[a] claim term used in multiple claims should be construed consistently." *Inverness Med. Switzerland GmbH v. Princeton Biomeditech Corp.*, 309 F.3d 1365, 1371 (Fed. Cir. 2002); *see also Fin Control Sys. Pty, Ltd. v. OAM, Inc.*, 265 F.3d 1311, 1318 (Fed. Cir. 2001) (stating that there is a "presumption that the same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims").

Further, courts are to avoid constructions that include unnecessary or superfluous language. *See, e.g., Diamond Coating Techs., LLC v. Hyundai Motor Am.*, No. 8:13-CV-01480-MRP, 2014 WL 5698445, at *11 (C.D. Cal. Aug. 25, 2014) ("Unnecessary language may inject ambiguity in the Court's construction or invite the trier of fact to interpret the Court's construction, thus defeating the purpose of claim construction."); *Am. Patent Dev., Corp. v. Movielink, LLC*, 604 F. Supp. 2d 704, 715 (D. Del. 2009) (refusing to adopt a construction that introduced "unnecessary verbiage and limitations into the claims").

Pfizer's proposed constructions, discussed below, reflect how the terms would be interpreted by a person of ordinary skill in the art ("POSA") as of the time of the application in light of the intrinsic record of which they would have been aware.

POINT II

PERSON OF ORDINARY SKILL IN THE ART

The person of ordinary skill in the art ("POSA") seeking to understand, make, and use the inventions of the '363 patent would have drawn on education and experience in several scientific fields. A POSA with respect to the '363 patent would have the knowledge of a pharmaceutical research scientist and/or clinician with experience developing drugs and using them to treat the cardiac arrhythmias and heart failure. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 962 (Fed. Cir. 1986) ("The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art."); (*see also* Chyall Decl. at ¶ 14). The person of ordinary skill in the art would have a doctor of medicine (M.D.) and/or doctor of philosophy (Ph.D.) degree in the relevant fields, including chemistry, pharmacology, and medicine. The person of ordinary skill in the art would also have experience in drug research and development, including experience analyzing pharmaceutical compounds based on analytical tests, such as differential scanning calorimetry, powder X-ray diffraction patterns, or infrared spectrum analyses, and clinical experience with pharmaceuticals used to treat cardiac arrhythmias and heart failure.

POINT III

CLAIM TERM: "ABOUT [ ]°C"

Pfizer's construction	**Defendant's constructions**
"within 1°C of [ ]°C" (claims 1, 11, 17)	"within the range of 161.7° C to 164.1° C" (claim 1) "160.0° C ± 0.3° C" (claim 11) "144.0° C ± 0.3° C" (claim 17)

"[T]he word 'about' does not have a universal meaning in patent claims, and . . . the meaning depends on the technological facts of the particular case. . . . Its range must be interpreted in its technologic and stylistic context." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). Courts have found that "about" is given its plain and ordinary meaning of "approximately," without any numerical limitation, when the "intrinsic evidence does not offer sufficient guidance to determine a specific range." *Takeda Pharm. Co. v. Handa Pharm., LLC*, No. C-11-00840 JCS, 2012 WL 1243109, at *25 (N.D. Cal. Apr. 11, 2012). To determine whether the intrinsic evidence supports a specific range, courts consider the "context" of the term, how "the term . . . was used in the patent specification, . . . other claims [, and] . . . the effects of varying that parameter." *Pall*, 66 F.3d at 1217.

Pfizer's proposed construction of the term "about [ ] °C" in each of claims 1, 11 and 17 as "within 1°C of [ ]°C" is supported by the intrinsic evidence. The specification of the '363 patent explains that the claimed dofetilide polymorphs are characterized by distinct endothermic thermal events when analyzed by DSC. (*See* Ex. A. at 2:13-24, 2:62-64, 3:14-16; *see also id.* at Figures 8, 9, 11); (Chyall Decl. at ¶¶ 20-21). The specification states that these endothermic thermal events occur at *about* 162° C, 160° C, and 144° C for dofetilide polymorphs P162, P162a and P143, respectively. (*See* Ex. A. at 2:13-24, 2:62-64, 3:14-16).

Claim 1 of the '363 patent claims a ". . . dofetilide polymorph P162 which is characterised by differential scanning calorimetry (DSC) in which it exhibits an endothermic thermal event at about 162° C." (emphasis added). Claim 11 claims a ". . . dofetilide polymorph P162a which is characterised by DSC in which it exhibits an endothermic thermal event at about 160° C." (emphasis added). Thus, "about [ ] °C" should be construed to mean "within 1°C of [ ]°C," as Pfizer proposes, so as to avoid overlap of the claimed endothermic thermal event range for P162 in Claim 1 and the range for the P162a in Claim 11. *See Ortho-McNeil Pharm.*, 476 F.3d at 1327 (construing the term "about 1.5" to avoid "encompass[ing] a range of ratios that could potentially render meaningless another claim's limitation, namely the 1:1 limitation"). Further, the term "about [ ] °C" should be construed consistently in claims 1, 11 and 17. *See Fin Control Sys.*, 265 F.3d at 1318 (claim term used in multiple claims should be construed consistently).

Tiger's proposed constructions are improper for several reasons. First, Tiger asks the Court to construe the term "about [ ] °C" inconsistently from claim to claim. There is no basis for Defendant's contention that the term "about [ ]°C" has distinct meanings in claims 1, 11 and 17. In each of those claims, "about [ ]°C" is being used in the same context: the temperature range for the endothermic thermal event in a DSC analysis for a dofetilide polymorph.

Moreover, there is no basis for construing the term "about [ ] °C" in claims 1, 11 and 17 to mean the specific temperature ranges that Tiger proposes for each claim. (*See* Chyall Decl. at ¶¶ 22-26). Tiger's proposed construction of the term "about [ ] °C" in claim 1 (range of 161.7° C to 164.1° C for P162) appears to be based on the peak and onset numbers reported in Example 7 in Table 2 of the '363 patent. Similarly, Tiger's proposed construction of the term "about [ ] °C" in claim 17 (144° C ± 0.3° C for P143) seems to reflect the peak temperature for

P143 reported in Table 2 in the '363 patent (listed at 144.3° C). (*See* Chyall Decl. at ¶ 24). However, Tiger's attempt to import specific and inconsistent limitations into the claims based on the data from certain examples in the '363 patent specification is wholly improper. *See Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988) ("Although the specification may aid the court in interpreting the meaning of disputed language in the claims, particular embodiments and examples appearing in the specification will not generally be read into the claims.").

In addition, a POSA would have understood that where a small set of sample DSC measurements are given, such as in the specification of the '363 patent, those samples are presumed to be representative and do not define the limits of an acceptable range. (*See* Chyall Decl. at ¶ 25). A POSA would have also understood that DSC measurements conducted on different samples in the same laboratory may differ by ± 0.5 °C, and that DSC measurements conducted in different laboratories will be in agreement to ± 1 °C. (*See id.*). Further, because an important use of DSC is assessing the relative stability of polymorphs, and because differences in melting point of less than 1° C do not indicate significant difference in stability, a POSA would not understand a measured endothermic event occurring "about" a given temperature to be limited to "± 0.3° C." (*See id.* at ¶¶ 19, 26). Therefore, a POSA would not have limited "about" to "± 0.3° C" as Tiger suggests. (*See id.* at ¶ 26).

Accordingly, the term "about [ ] °C" should be construed throughout as Pfizer proposes.

POINT IV

CLAIM TERM "DOFETILIDE POLYMORPH [P162/P162a/P143] WHICH IS CHARACTERISED BY [DIFFERENTIAL SCANNING CALORIMETRY (DSC)] IN WHICH IT EXHIBITS AN ENDOTHERMIC THERMAL EVENT AT ABOUT [162/160/144]° C"

Pfizer's construction	**Defendant's constructions**
"dofetilide polymorph [P162/P162a/P143] exhibiting a temperature at which the endothermic peak has its maximum value within 1° C of [162/160/144]° C when analyzed by differential scanning calorimetry (DSC)" (claims 1, 11, 17, respectively)	"dofetilide polymorph P162 which exhibits a temperature at which the endothermic peak has its maximum value within the range of 161.7° C to 164.1° C when evaluated using differential scanning calorimetry (DSC) that distinguishes it from other polymorphic forms" (claim 1) "dofetilide polymorph P162a which exhibits a temperature at which the endothermic peak has its maximum value at 160° C ± 0.3° C when evaluated using DSC that distinguishes it from other polymorphic forms" (claim 11) "dofetilide polymorph P143 which exhibits a temperature at which the endothermic peak has its maximum value at 144° C ± 0.3° C when evaluated using DSC that distinguishes it from other polymorphic forms" (claim 17)

The Tiger's proposed constructions of these terms differ in two substantive ways: (1) the meaning of "about [ ] °C"; and (2) Tiger's inclusion of the phrase "that distinguishes it from other polymorphic forms" in its proposed constructions of claims 1, 11, and 17. With respect to the meaning of the claim term "about [ ] °C," the Court should adopt Pfizer's proposed construction of "within 1°C of [ ]°C" for reasons discussed *supra* in Point III. (*See also* Chyall Decl. at ¶¶ 22-26).

Tiger's addition of the phrase "that distinguishes it from other polymorphic forms" in its proposed constructions improperly expands upon the language of the claims. The parties agree that the dofetilide polymorph of each of claims 1, 11, and 17 is "characterised by" an "endothermic thermal event" when the polymorph "exhibit[s] a temperature at which the endothermic peak has its maximum value within"[3] a certain temperature range. This is based on the plain and ordinary meaning of the claim term.

Tiger's insertion of the phrase "that distinguishes it from other polymorphic forms" in its proposed constructions is not necessary to convey the plain and ordinary meaning of the claim term. Claims 1, 11, and 17 of the '363 patent themselves distinguish dofetilide polymorphs P162, P162a, and P143 based on DSC analyses that characterize each polymorph. *See also* Ex. A. at 2:13-24, 2:62-64, 3:14-16 (the '363 patent specification describing the DSC analytical results that characterize different dofetilide polymorphs). Accordingly, the Court should adopt Pfizer's proposed constructions and decline to adopt Defendant's proposed constructions because the phrase "that distinguishes it from other polymorphic forms" is unnecessary. *See, e.g.*, *Diamond Coating Techs., LLC v. Hyundai Motor Am.*, No. 8:13-CV-01480-MRP, 2014 WL 5698445, at *11 (C.D. Cal. Aug. 25, 2014) ("Unnecessary language may inject ambiguity in the Court's construction or invite the trier of fact to interpret the Court's construction, thus defeating the purpose of claim construction."); *Am. Patent Dev., Corp. v. Movielink, LLC*, 604 F. Supp. 2d 704, 715 (D. Del. 2009) (refusing to adopt a construction that introduced "unnecessary verbiage and limitations into the claims").

[3] Pfizer's construction uses "exhibiting" as opposed to "exhibits a."

CONCLUSION

For the reasons set forth above, the Court should construe (i) the term "about [ ] °C" in each of claims 1, 11, and 17 as "within 1°C of [ ]°C" and (ii) the term "dofetilide polymorph [P162/P162a/P143] which is characterised by [differential scanning calorimetry (DSC)] in which it exhibits an endothermic thermal event at about [162/160/144]° C" in each of claims 1, 11 and 17 as "dofetilide polymorph [P162/P162a/P143] exhibiting a temperature at which the endothermic peak has its maximum value within 1° C of [162/160/144]° C when analyzed by differential scanning calorimetry (DSC)."

Dated: February 4, 2015

/s/ Laurie L. Proctor

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CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of February 2015, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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